

**REMARKS**

***Status of the Claims***

Claims 23, 25-27, 30-34, 36, 39, 40, 42-48, 50-56 and 62-67 were in the application.

Claims 23, 25-27, 30-34, 36, 39, 40, 42-48, 50-56 and 62-67 have been rejected.

Claims 23, 25-27, 30-32, 34, 36, 39, 40, 42, 43, 45, 48, 50, 52, 55, and 62-67 have been amended.

Upon entry of this amendment, claims 23, 25-27, 30-34, 36, 39, 40, 42-48, 50-56 and 62-67 will be pending.

***Summary of Amendment***

The claims have been amended to correct alleged typographical errors. The claims have also been amended to recite that the active agent or the therapeutic agent is a cytostatic or cytotoxic agent. In addition, claims 23, 42 and 48 have been amended to recite that the compositions can be used to treat metastatic colorectal cancer. Support for the claims is found throughout the specification, no new matter has been added.

***Objections***

The Office objects to the abstract for allegedly being more than 150 words. Applicants have amended the abstract to be no more than 150 words. In view of the amendment, Applicants respectfully request that the objection to the abstract be withdrawn.

Claim 67 was objected to for typographical errors. Applicants have amended claim 67 correcting the typographical errors rendering the objection moot.

Claims 25, 27, 32, 34, 40, 43, 45, 50, 52, and 62-66 stand objected to for alleged informalities. The Office alleges that the claims require a definite article (*e.g.* "the") prior to the phrase "amino acid sequence of SEQ ID NO: 2." Applicants respectfully assert that the claim does not require a definite article, but solely in order to further prosecution applicants have replaced the article "an" with the article "the" as expressly requested by the Office.

Claims 25, 32, 43, 45, 50, and 62-66 also stand objected to for alleged typographical errors. Applicants have amended claims 25, 32, 43, 45, 50, and 62-66 to correct the alleged typographical errors rendering the objection moot.

In view of the foregoing, Applicants respectfully request that the objections be withdrawn.

***Double Patenting Rejection***

Claims 23, 25-28, 33, 34, 38 and 40 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5 and 6 of U.S. Patent No. 5,962,220.

Claims 23, 25-28, 33, 34, 38 and 40 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-10 and 13 of U.S. Patent No. 6,087,109.

Claims 23 and 28 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24, 26, 28, 29 and 33-41 of U.S. Patent No. 7,097,839.

Claims 23, 25-28, 33, 34, 38, 40, 41, 42, 45 and 47 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 6, 10 and 12 of U.S. Patent No. 5,962,220 in view of Gluck.

As noted in previous responses, once claims have been indicated to be allowable, Applicant shall promptly provide Terminal Disclaimer as appropriate. To that end, the Examiner is invited to contact Applicant's undersigned representative and inform him of the allowability of the claims so that a Terminal Disclaimer can be promptly filed.

***Provisional Double Patenting Rejection***

Claims 23, 25-27, 48, 50, 51, 52, 54 and 55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 12 and 15-17 and 20-22 of copending Application No. 11/494,901 (US 20060269477). Although the

conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention in the '901 application reads on the instant claimed invention.

This rejection is provisional. As the co-pending application has not yet issued, no action is required at this time.

***Claim Rejections Under 35 U.S.C. § 112, First Paragraph***

Claims 23, 25-27, 30-34 36, 39, 40, 42-48, 50-56, 62-67 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled. The Office alleges that “while being enabling for using the pharmaceutical compositions in isolated cells” the specification allegedly “does not reasonably provide enablement for pharmaceutical uses in animals or humans.” (Office Action, page 5). Applicants respectfully disagree.

The claims are enabled because one of skilled in the art would be able to practice the claimed invention without undue experimentation. The Office has failed to meet its burden to demonstrate that undue experimentation would be required to practice the claimed invention. The Office’s analysis of the presently claimed invention under the *Wands* factors is erroneous and, therefore, leads to an incorrect conclusion that the presently claimed invention is not enabled.

***Breadth of Claims***

The Office’s analysis under the first *Wands* factor, the breadth of the claims, is improper. The Office alleges that the “breadth of the claims seems to encompass pharmaceutical compositions ...with intended therapeutic uses in animals or humans for treatment of any disease.” The Office alleges that the present application does not describe using the “claimed peptides” as parts of pharmaceutical compositions to treat any disease and any certain uses are prophetically discussed. Applicants respectfully assert that the Office is misconstruing the claims with respect to the breadth of the claims.

Applicant respectfully asserts that it is well settled that there is no requirement to recite the intended use in a composition claim. The absence of such an intended use is not an assertion

that the composition can be used for any purpose. The inclusion of references to an intended use does not alter the scope of a claim.

The presently claimed invention is directed to pharmaceutical compositions. In assessing the breadth of the claims, the Office has erroneously concluded that Applicant has asserted that the claimed composition can be used to treat any disease. No such claim has been made and the importation by the Office of such a feature into claims is wholly improper. The scope of the claims is clear and there is no such feature recited. By analyzing the claim to contain features which are not recited, the Office has reached an erroneous conclusion with respect to the Breadth of Claims factor.

Nevertheless, solely in an effort to advance prosecution, Applicants respectfully note that an intended use has been added to claims 23, 42 and 48 specifically referring to the treatment of metastatic colorectal cancer.

***The state of the prior art/The Predictability or lack thereof in the art***

Applicant respectfully asserts that the Office has not provided any evidence nor offered any reasoning to support its contention that the invention is not enabled because of unpredictability in the art. The references cited by the Office do not support the position taken by the Office and the reasoning used in their application in the *Wands* analysis is flawed.

The Office alleges that the “utilization of peptides as pharmaceutical compositions...is highly unpredictable.” (Office Action, page 7) The Office alleges that the treatment of “various disease” is also highly unpredictable. (Office Action, page 7).

The Office cites Cianfrocca *et al.* (British Journal of Cancer 2006, pp. 1-6) as evidence that the art is highly unpredictable. Applicant respectfully disagrees and assert that Cianfrocca supports the conclusion that the presently claimed invention is enabled.

The Office alleges that the claims are not enabled because it is alleged that the use of peptides to treat human diseases is unpredictable. The Office asserts that Cianfrocca is evidence of this unpredictability because Cianfrocca report only “limited success” with a peptide drug candidate that they were testing. Applicant respectfully asserts that for the purpose of assessing predictability, limited success is sufficient. While Cianfrocca may suggest that it is

unpredictable whether a peptide drug will have sufficient efficacy to support marketing approval, such predictability is not required in assessing compliance with the enablement requirement. Cianfrocca reports that the peptide drug being tested showed some degree of efficacy. Therefore Cianfrocca does not support an assertion that the art is unpredictable. Rather, Cianfrocca tends to support the assertion that it is predictable that peptide drug candidates will have some activity.

The Office is applying the wrong standard in what is required to be predictable. The Office's error is based upon an incorrect assumption that the use of peptides is unpredictable because there is no reasonable expectation of success that a peptide drug candidate will demonstrate sufficient efficacy to be granted marketing approval by a regulatory agency such as the FDA. Applicant respectfully asserts that whether there is a reasonable expectation that a drug will have some efficacy and whether there is a reasonable expectation that a drug will have sufficient efficacy to receive marketing approval are two different questions, of which only the former is relevant in assessing enablement.

The Office alleges that the "difference between FDA standards and patentable difference is irrelevant." On the contrary, the law is quite clear that the two standards are quite different. As explained in *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995), the Office should not confuse "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug," citing *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994). Under the law, one cannot conclude that the art is unpredictable because of the unpredictability of finding marketable drugs.

When the proper standard is applied, Cianfrocca provides no basis to question the predictability of the art and demonstrates that the presently claimed invention is enabled. As noted above, the Office characterizes Cianforra as having only "limited success." Regardless of the degree or level of "success" that is reported in Cianforra, Cianforra shows that the pharmaceutical compositions can be used without undue experimentation. The law does not require that a pharmaceutical compositions be curative or have a certain threshold level of "success" in order to establish patentability. The ability of the drug to achieve limited success is not evidence of unpredictability but rather evidence that the peptides in Cianfrocca demonstrated

success rather than complete failure. The compounds may have failed as drug candidates in the context of developing a drug that will be approved by the FDA but the limited success achieved is sufficient for the purposes of evaluating patentability. Cianfrocca indicates that the disclosed compositions had some degree of positive effect. As such, it does not provide any evidence that the art is unpredictable but, on the contrary, supports Applicant's position.

Additionally, the Office refers to the "mode of delivery" and that the mode "is also critical" and the "success of the delivery is highly unpredictable." The Office refers to Russell-Jones, which allegedly states that peptides and protein pharmaceuticals are "highly susceptible to proteolysis and also have very low oral bioavailabilities." (Office Action, pp. 7-8). Regardless of whether or not Russell-Jones is correct, the level of bioavailability or the level of proteolysis for orally delivered peptides is not relevant to the determination of whether the presently claimed invention is enabled. There is no requirement that a pharmaceutical composition be expected to be active by every mode of administration in order to be enabled. Applicant is aware of no such authority which supports a conclusion that pharmaceutical compositions are deemed not enabled if they cannot be administered orally. Evidence that oral administration is unpredictable does not establish that one skilled in the art would doubt the Applicant's assertion of enablement.

Importantly, the claims contain the limitation that the pharmaceutical compositions are injectable. The position of the Office that the art is unpredictable because peptides cannot be delivered orally is not even applicable to the claimed invention which refer to compositions that are not orally delivered. The citation of Russell-Jones as evidence supporting the unpredictability in the art is completely misplaced since the claimed invention is not delivered by the route of administration discussed in Russell-Jones.

El-Andaloussi et al (Current Pharmaceutical Design. Vol. 11: 3597-3611; 2005), is cited in the Official Action in support of the assertion that the invention is not enabled because delivery of peptide drugs to the inside of cells to exert their pharmaceutical effects is not predictable because the cell membrane prevents entry of peptides into cells. The Office asserts that the instant specification has not shown that the claimed peptides can penetrate cells, or demonstrating their specific cell-penetrating structures and/or properties. The problems

disclosed in El-Andaloussi are not present in the delivery of the peptides in the present invention. The peptides specifically bind to ST receptors, which allows the peptides to specifically overcome the problems discussed in El Andaloussi et al. As noted on page 9, lines 29-31 of the specification, the peptides of the instant invention specifically bind to a receptor (ST receptor) which is present on the cell membrane that is exposed to the outside of the cell, after which the receptor and bound ligand are internalized. The Office alleges that the specification does not "specifically define the ST receptor as a cell membrane protein." (Office Action, page 13). One skilled in the art knows and understands that the ST receptor is a cell membrane protein. Additionally, the present specification states that the ST receptor is a membrane protein (See, paragraphs 41 and 42 of the published application). Therefore, one skilled in the art recognizes that ST receptors are cellular receptors and that the problems discussed in El Andaloussi are not issues in the enablement of the present invention. Applicant urges that El Andaloussi et al. does not support a finding of non enablement.

The Office also cites Voskoglou-Nomiko et al (Clinical Cancer Research. Vol. 9: 4227-4239; 2003) in support of the position that *in vitro* testing for treatment of diseases such as cancer cannot be reliably correlated to successful treatments in animals or humans. As discussed above, the successful treatments in animals or humans is considered to be sufficiently effective to support FDA marketing approval and such success is not required for patentability. The standards in evaluating enablement do not require such a level of efficacy. Additionally, one of skill in the art reading Voskoglou-Nomiko would understand that the presently claimed invention is enabled. In contrast to stating that there is no correlation, Voskoglou-Nomiko emphasizes the use of *in vitro* cells to predict the alleged success that the Office would require for enablement. Voskoglou-Nomiko et al state on page 4237 that "[t]he work presented here argues for emphasis to be placed on *in vitro* cell lines..." In the Conclusions section of the Abstract on page 4227, Voskoglou-Nomiko et al states, "These results suggest that under the right framework and when panels are used, the *in vitro* cell line and human xenograft models may be useful in predicting the Phase II clinical trial performance of cancer drugs." Applicant respectfully urges that one skilled

in the art would not conclude that the claimed invention is not enabled in view of Voskoglou-Nomiko et al.

The predictability for the presently claimed invention does not require that one of skill in the art to be able to reasonably predict a level of clinical success sufficient to achieve regulatory approval or to reasonably predict efficacy by all routes of administration. In contrast to the Office's interpretation of predictability, predictability should focus on whether one of skill in the art can make and use the presently claimed pharmaceutical compositions. The Office has not alleged that one could not make the composition. The Office's allegation that the claims lack enablement is based upon an assertion of unpredictability of the field of peptide drugs. The evidence relied upon, however, is insufficient to support the conclusion reached by the Office. Cianfrocca shows a peptide drug have activity in clinical experiments. Although the level of activity was disappointing with respect to its prospects for achieving regulatory approval and commercial success, the level of activity was sufficient for the purposes of patentability and the reference does not support a finding that the field of peptide drugs is unpredictable. Russell-Jones shows difficulties in delivery of peptides by oral administration. As discussed above, the presently claimed invention refers to injectable compositions. Russell-Jones is not useful evidence in assessing the enablement of the claimed invention. The issues for which El Andaloussi was cited in support of are not analogous in the instant claimed invention. The peptides in the instant invention are targeted to a membrane protein. The citation of Voskoglou-Nomiko et al. does not establish that the art is unpredictable. Voskoglou-Nomiko et al. indicates one skilled in the art would find *in vitro* data sufficiently reliable to justify human testing.

Applicants respectfully asserts that the reasoning and evidence provided do not establish that the state of the art is unpredictable for the purposes of evaluating enablement of the claimed invention.

***Remaining Wands Factors***

The Office admits that the level of skill would be high. The Office alleges that there are no working examples indicating "effects on any postulated diseases." The Office alleges that there are no working examples to "demonstrate the pharmaceutical uses of the claimed peptides



and their conjugates.” (Office Action, page 9). As was the case for the other factors discussed above, the Office is applying the incorrect standard. The Office is requiring that for the pharmaceutical compositions to be enabled the Applicants must show efficacy or “success.” The Office relies upon *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 1216-1217, to support this conclusion. The facts in *Amgen*, however, differ significantly from those in the present case such that the holding does not properly apply.

In *Amgen*, the claims were directed to preparations of erythropoietin (EPO). The Federal Circuit held that “despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them.” The Federal Circuit found that the subject matter claimed in *Amgen* was insufficiently disclosed to allow a person of skill in the art to make the claimed subject matter. In contrast to *Amgen*, Applicants have provided sufficient guidance with respect to the disclosure of the claimed subject matter to allow one skilled in the art to make the pharmaceutical compositions. There has been no assertion by the Office that the specification does not provide sufficient guidance to make the claimed invention.

The other claims at issue in *Amgen* recited a functional limitation requiring a specific, enumerated level of activity of EPO *in vivo*. The Federal Circuit held that there was not sufficient evidence to demonstrate that the specific, enumerated level of activity of EPO *in vivo* was enabled by the subject matter disclosed in the specification. In contrast to the claims at issue in *Amgen*, none of the pending claims recite a specific, enumerated level of activity *in vivo* or otherwise. The *Amgen* claims required that the protein not simply be active *in vivo* but that it display a specific, measurable level of activity. The invention defined in *Amgen* had a quantifiable level of activity and the court held that that invention was not enabled because the specification did not enable the EPO with the quantified level of activity *in vivo*. The instantly claimed invention contains no such analogous required quantifiable level of activity. The enablement analysis for the instant invention is whether the specification enables one skilled in the art to make and use the composition as claimed. The claims merely require that the composition be expected to have some level of activity. The claims in *Amgen* required that the

composition be expected to have a defined level of activity. The claimed invention determines what must be predictability in the enablement analysis and the differences between the invention in *Amgen* underlie the differences in what must be disclosed and what must be predictable to comply with the enablement requirement.

Accordingly, the presently claimed invention is enabled because those skilled in the art would accept the objective truth of Applicant's assertion that the claimed invention can be practiced without undue experimentation. The Office has failed to meet its initial burden to establish that those skilled in the art would not accept the objective truth of Applicant's assertion that the claimed invention can be practiced without undue experimentation. The reasoning and evidence provided by the Office do not support a finding that those skilled in the art would question the enablement of the claimed invention. In the absence of reasoning and evidence sufficient to meet the Office's burden, the Applicant's assertions are accepted and the claims are concluded to be enabled.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

***Claim Rejections Under 35 U.S.C. § 103***

***Houghten in view of Hussain, Trouet and Gluck***

Claims 23, 25-27, 30, 32-34, 42-43, 45-48, 50-56, and 62-67 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Houghten (WO 84/02700) in view of Hussain et al (EP 0341661), Trouet et al (PNAS 79: 626-629 (1982) and Gluck (U.S. Patent 6,040,167).

Houghten discloses the preparation of synthetic ST peptides and their use as immunogenic target components in vaccines against enterotoxigenic strain of *E. coli* to protect an individual from intestinal colonization by such bacteria and the acute diarrhea and intestinal stress caused thereby.

Hussain discloses the addition of a non-peptide carrier molecule to improve uptake and bioavailability of drugs delivered into mucosal tissue.

Troute is cited as teaching the conjugation of non-peptide drugs to peptides in order to provide selective targeting of anti-tumor drugs.

Gluck discloses liposomes.

The Office asserts that the claims are *prima facie* obvious. Applicant respectfully disagrees.

The claimed invention is a pharmaceutical composition comprising an ST receptor binding ligand in combination with a non-peptide, radiostable cytotoxic or cytostatic agent.

Houghten neither teaches nor suggests combining the disclosed peptides with a cytotoxic or cytostatic agent. One skilled in the art would not consider making such a combination based upon the teachings in Houghten since Houghten teaches making a vaccine and one skilled in the art would not consider combining the peptides with a cytotoxic or cytostatic agent in making a vaccine. The claimed compositions comprising cytotoxic or cytostatic agents in combination with the ST receptor binding ligands are used to treat metastatic cancer. Following the teachings of Houghten for making a vaccine, one skilled in the art would not consider adding cytotoxic or cytostatic agents to arrive at the claimed invention. One of skill in the art would not have combined the synthetic ST peptides with a cytotoxic or cytostatic agent because it would have been contrary to the purpose of generating an immune response for the purposes of a vaccine. An element that when combined with another reference that would be contrary to the purpose of the primary reference cannot render the combination obvious. Accordingly, the presently claimed invention is not obvious.

Combining Houghten with Hussain doesn't render the claimed invention obvious Hussain *et al* teaches away from the claimed invention. Hussain *et al* is directed to absorption enhancers for improving uptake of drugs delivered into mucosal tissue. It is asserted that one skilled in the art would combine the teachings of Hussain and Houghten because Hussain teaches that the addition of the non-peptide carrier improves bioavailability. Hussain teaches away from the claimed invention and does not render the claimed invention obvious when combined with Houghten and the teachings of the other cited references.

The claims recite that the pharmaceutical composition is an injectable pharmaceutical composition. As such, Hussain et al. teaches away from each of the pending claims. Specifically, Hussain et al teaches making compounds more amenable to absorption based, non-injection routes of administration. One skilled in the art would not use an absorption enhancer taught by Hussain et al. to modify Houghten in the preparation of an injectable pharmaceutical compositions. Hussain et al. teaches away from combining with Houghten and teaches away from the presently claimed invention.

Trouet et al. discloses linking a known anti-tumor drug to a molecule which selectively binds to another molecule on a tumor cell in order to deliver the anti-tumor drugs to tumor cells. One skilled in the art would not use the tumor targeting taught by Trouet et al. to modify Houghten and Hussain in the preparation of injectable pharmaceutical compositions of the claimed invention. As noted above, Hussain teaches away from the claimed invention. Houghten teaches vaccines and makes no disclosure with respect to anti-tumor agents. One skilled in the art would not use the Trouet's teachings of improved anti-cancer compositions to modify the vaccine taught by Houghten, regardless of whether Houghten modified the vaccine according to Hussain in disregard to the teachings in Hussain for delivery by absorption to mucosal tissue.

Gluck, as discussed above, discloses liposomes and does not cure the deficiencies in the present rejection.

The combination of references do not establish a *prima facie* case that the claimed invention is obvious. One skilled in the art would not combine the references to make the claimed invention. Houghten teaches immunogens for vaccines, making it incompatible with Trouet's teaching of tumor targeting anti-cancer drugs. Hussain teaches away from injectable compositions as claimed. Applicants respectfully urge that there is no motivation to combine Houghten with Trouet and that the further combination of Hussain to make the present invention contradicts the teachings of Hussain. Applicants respectfully urge that there is no common sense reason why one skilled in the art having knowledge of the art would include anti-cancer modifications taught by Trouet to the vaccines in Houghten. Houghten teaches peptides useful

as an immunogenic target of a vaccine and there is no reason why one skilled in the art would conjugate anti-cancer drugs to it. It is well established that the reason for combining references may not be based upon the teachings in the application being examined. One skilled in the art would not combine the references. No prima facie case of obviousness has been established.

Accordingly, the claims are non-obvious. Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 103(a) as being unpatentable over Houghten et al. in view of Hussain et al, Trout et al, and Gluck be withdrawn.

***Houghten in view of Hussain, Trout, Gluck and Lee***

Claims 23, 25-27, 30-34, 36, 39, 40, 42-48, 50-56, and 62-67 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Houghten (WO 84/02700), in view of Hussain et al (EP 0341661), Trout et al (PNAS 79: 626-629 (1982) and Gluck (U.S. Patent 6,040,167) and Lee et al (U.S. Patent 5,183,805).

Houghten, Huassain, Trouet and Gluck are discussed above.

Lee et al. discloses conjugating non-peptide drugs including 5-fluorouracil to peptides for cancer therapeutics.

As noted above, one skilled in the art would not combine Houghten, Hussain, Trouet and Gluck. Houghten discloses a vaccine which would not be combined with cytotoxic or cytostatic agents. One skilled in the art would not modify the vaccine peptides disclosed in Houghten by conjugating anti-cancer compounds as by Trouet. One skilled in the art would not use the teachings in Hussain to make an injectable composition. Nothing in Lee changes any of the shortcomings and contradictory and incompatible teachings in the assertions by the Office that the combination of references renders the claims obvious. One skilled in the art would not combine Houghten, Hussain, Trouet, Gluck and Lee to make the instantly claimed invention. The combination of Houghten, Hussain, Trouet, Gluck and Lee does not render the claimed invention prima facie obvious.

The claims are not obvious in view of Houghten et al in view of Hussain et al and Trouet et al., Gluck et al. and further in view of Lee et al. Applicant respectfully requests that the

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rejection of the claims under 35 U.S.C. §103(a) as being unpatentable over Houghten et in view of Hussain et al , Gluck et al, Trouet et al. and Lee et al. be withdrawn.

***Conclusion***

Claims 23, 25-27, 30-34, 36, 39, 40, 42-48, 50-56 and 62-67 are in condition for allowance. A notice of allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully Submitted,

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